

13-valent Pneumococcal Conjugate Vaccine for Adults (PCV13)

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Pneumococcal Vaccines Work Group

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13-valent Pneumococcal Conjugate Vaccine (PCV13) for Adults

- Licensed for use among adults ≥ 50 years old on 12/30/11
- FDA approved under the Accelerated Approval Pathway
- Based on non-inferior immunogenicity compared to PPSV23
- Indications
 - Prevention of pneumococcal disease (including pneumonia and invasive disease) in adults 50 years of age and older
 - Prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F
- Post-approval condition of licensure: Randomized controlled trial of PCV13 against pneumococcal pneumonia among adults ≥ 65 years old in the Netherlands

Pneumococcal Vaccines Work Group: Terms of Reference

- Review data on immunogenicity, efficacy, and cost-effectiveness of pneumococcal conjugate vaccines in adults
- Determine whether data available to date on PCV13 immunogenicity and cost-effectiveness are sufficient to determine value of immunizing adults with PCV13
- Develop a revised statement on pneumococcal immunization if determined that one including PCV13 recommendations for adults is necessary

Summary of Data Presented: PCV13 for Adults

- Evidence reviewed and presented to ACIP
 - Immunogenicity results from Phase III studies (Pfizer)
 - Immunogenicity data for PCV from published literature
 - Cost-effectiveness and public health impact of different adult pneumococcal vaccination strategies
- Evidence NOT available to help with decision-making
 - Efficacy against pneumonia (Netherlands trial, 2013)
 - Indirect (herd) effects of PCV13 use in children

Tentative Timeline for ACIP Meetings

ACIP Meeting	Topic	Vote?
Feb 2012	Present GRADE evidence for adults ≥ 65 years old and for immunocompromised adults	No
June 2012	Potential vote on immunocompromised adult recommendations. Update on indirect effects from use of PCV13 in children	Yes
Oct 2012	Update on indirect effects from use of PCV13 in children	No
Feb 2013	Report on CAPITA trial results, if available. Update on indirect effects from use of PCV13 in children.	Possible
June 2013	Report on CAPITA trial results, if available. Update on indirect effects from use of PCV13 in children.	Likely

Pneumococcal Vaccines Work Group

Today's Presentations

- Considerations for Use of 13-valent Pneumococcal Conjugate Vaccine among Adults ≥ 65 Years Old
 - Background, Review of Data, and GRADE
 - Ms. Tamara Pilishvili
- Considerations for Use of 13-valent Pneumococcal Conjugate Vaccine among Adults with Immunocompromising Conditions
 - Background, Review of Data, and GRADE
 - Dr. Kathleen Dooling